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Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/818,228
Filing Date	March 27, 2001
First Named Inventor	Kent L. Christopher
Group Art Unit	3761
Examiner Name	M. Patel
Total Number of Pages in This Submission: 69	Attorney Docket Number: 1246/39(a)

ENCLOSURES *(check all that apply)*

- [x] Fee Transmittal Form
  - [x] Fee Attached
- [ ] Amendment / Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
  - [ ] Response to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Assignment Papers *(for an Application)*
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
- [ ] After Allowance Communication to Group
- [ ] Appeal Communication to Board of Appeals and Interferences
- [x] Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
- [ ] Proprietary Information
- [ ] Status Letter
- [ ] Other Enclosure(s) *(please identify below)*:

"Brief for Appellant" in triplicate

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	**Thomas S. Birney** **Dorr, Carson, Sloan & Birney, P.C.**
Signature	Thomas S Birney
Date	**April 4, 2003**

CERTIFICATE OF MAILING

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Typed or printed name	**Thomas S. Birney**	**Express # EV 260289449 US**	
Signature	Thomas S Birney	Date	**April 4, 2003**

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FEE TRANSMITTAL for FY 2003

Effective 01/01/2003. Patent fees are subject to annual revision.

☑ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 160

Complete if Known	
Application Number	09/818,228
Filing Date	March 27, 2001
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METHOD OF PAYMENT *(check all that apply)*

☑ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☑ Deposit Account:

Deposit Account Number: 04-1414

Deposit Account Name: Dorr, Carson, Sloan & Birney, P.C.

The Commissioner is authorized to: *(check all that apply)*

☐ Charge fee(s) indicated below ☑ Credit any overpayments

☑ Charge any additional fee(s) during the pendency of this application

☐ Charge fee(s) indicated below, **except for the filing fee** to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	750	2001	375	Utility filing fee	
1002	330	2002	165	Design filing fee	
1003	520	2003	260	Plant filing fee	
1004	750	2004	375	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

		Extra Claims		Fee from below	Fee Paid
Total Claims	-20** =		X		=
Independent Claims	- 3** =		X		=
Multiple Dependent					=

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	84	2201	42	Independent claims in excess of 3
1203	280	2203	140	Multiple dependent claim, if not paid
1204	84	2204	42	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($)

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	410	2252	205	Extension for reply within second month	
1253	930	2253	465	Extension for reply within third month	
1254	1,450	2254	725	Extension for reply within fourth month	
1255	1,970	2255	985	Extension for reply within fifth month	
1401	320	2401	160	Notice of Appeal	
1402	320	2402	160	Filing a brief in support of an appeal	160
1403	280	2403	140	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,300	2453	650	Petition to revive - unintentional	
1501	1,300	2501	650	Utility issue fee (or reissue)	
1502	470	2502	235	Design issue fee	
1503	630	2503	315	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	750	2809	375	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	750	2810	375	For each additional invention to be examined (37 CFR 1.129(b))	
1801	750	2801	375	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($) 160

SUBMITTED BY				(Complete *(if applicable)*	
Name (Print/Type)	Thomas S. Birney	*Registration No. (Attorney/Agent)*	30,025	*Telephone*	(303) 333-3010
Signature	Thomas S Birney			*Date*	April 4, 2003

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This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**

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#17

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of Kent L. Christopher	
Serial No. 09/818,228	Examiner M. Patel Group Art Unit 3761
Filed: March 27, 2001	
For: METHOD AND APPARATUS FOR PHARYNGEAL AUGMENTATION OF VENTILATION	

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Thomas S Birney
Signature

April 4, 2003
Date Deposited

Thomas S. Birney

EV 260289449 US
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BRIEF FOR APPELLANT

Real Party in Interest

The Appellant, Kent L. Christopher, 9086 East Colorado Circle, Denver, Colorado 80231, is the owner of record of the application and is the real party of interest.

Related Appeals and Interferences

The Appellant does not know of any other appeals or interferences that would directly affect or be directly affected by or have any bearing on the Board's decision in the pending appeal.

Status of Claims

The application with claims 1 through 28 (including independent claims 1, 15, and 23) was filed on March 27, 2001.

In the first Office Action, mailed October 5, 2001, claims 1 - 28 were rejected. Specifically, claims 1 - 22 were rejected under 35 U.S.C. §101 for being directed to non-statutory subject matter because the claims positively recited a part of the human body. Claims 1 - 4, 8, 11 - 17, 19, 20, 23 - 25 and 28 were rejected under 35 U.S.C. §103(a) as being unpatentable over Brekke (U.S. Patent No. 3,915,173). (Paragraphs 2 and 17 of this Office Action apparently contain several typographical errors regarding the claim numbers in this rejection. However, the claims listed above appear to be correct based on the text and substance of the rejection.) Claims 5, 6, and 18 were rejected under 35 U.S.C. §103(a) as being unpatentable over Brekke in view of Dali et al. Claims 7 and 19 were rejected under 35 U.S.C. §103(a) as being unpatentable over Brekke in view of Spofford et al. Claims 9, 10, 21, 22, 26, and 27 were rejected under 35 U.S.C. §103(a) as being unpatentable over Brekke in view of Daniell et al.

In the Amendment filed on November 13, 2001, the Appellant amended claims 1 and 15 to address a rejection under 35 U.S.C. §101. The Appellant respectfully traversed the obviousness rejections of claims 1 - 28 and presented arguments in support thereof.

In the second Office Action, mailed January 31, 2002, the previous obviousness rejections of claims 1 - 28 were made final.

In the Amendment filed on March 19, 2002, the Appellant respectfully traversed the obviousness rejections of claims 1 - 28 and presented arguments in support thereof. The Amendment also amended claims 1, 15 and 23 to clarify that the present invention is an "open" system that does not obstruct the patient's spontaneous breathing, unlike the endotracheal tube disclosed by Brekke. An Advisory Action was mailed on April 11, 2002, refusing to enter this Amendment.

A Request for Continued Examination (RCE) was filed on April 17, 2002, along with a copy of the Amendment previous filed on March 19, 2002.

The third Office Action, mailed on May 2, 2002, continued the obviousness rejections of claims 1 - 28.

In the Amendment filed on July 23, 2002, claims 1, 15 and 23 were amended once again to further clarify that the present invention is an "open" system to supplement a patient's spontaneous respiration in treatment of respiratory failure, respiratory insufficiency, or sleep apnea syndrome, unlike Brekke.

A fourth, final Office Action, mailed on September 23, 2002, continued the obviousness rejections of claims 1 - 28.

A Request for Reconsideration was filed on December 18, 2002, discussing the differences in the structure between the present invention and Brekke, and also discussing the pathophysiology of respiratory failure, respiratory insufficiency, and sleep apnea. An Advisory Office Action was mailed on January 23, 2003.

This is an appeal from the final rejection of claims 1 - 28 by the final Office Action, dated September 23, 2002. Claims 1 - 28 are the subject of this appeal and are attached hereto, as finally rejected, in the Appendix. Any reference made herein to claim line numbers correspond to those appearing in the Appendix.

Status of Amendments

No amendments to the claims subsequent to the final rejection have been filed.

Summary of the Invention

This invention is a nasopharyngeal catheter for direct pharyngeal delivery of high flows of humidified air, oxygen, helium, or other gases to supplement ventilation of a spontaneously breathing patient. Flow rates in the range of approximately 4 to 40 liters per minute can be employed. In one embodiment, the flow passes through a heater that maintains a desired temperature, and a humidifier that maintains a desired relative humidity. The present invention may also include a nasal catheter that can be cut to a

desired length and removably attached to a horizontal delivery tube. Gas can be supplied through oxygen connections at either end of the horizontal delivery tube.

For example, the present invention can be used for the purpose of treating patients with respiratory failure or insufficiency, or sleep apnea syndrome. In a home setting, the present invention can be employed for nocturnal augmentation of patients with sleep apnea syndrome (obstructive, central, or mixed), or chronic respiratory failure or insufficiency resulting from emphysema (COPD), other obstructive lung diseases, interstitial lung diseases, pleural diseases, neuromuscular diseases, and other restrictive disorders. In a hospital setting, the present invention can be used to treat patients with acute respiratory failure/insufficiency or acute respiratory failure/insufficiency superimposed upon chronic respiratory failure/insufficiency. The present system can be used intermittently or throughout the day and night to augment ventilation and avoid the need for endotracheal intubation and conventional mechanical ventilation.

The present invention offers a number of advantages over the prior art in treatment of sleep apnea and respiratory failure/insufficiency. No surgical procedure is required. The device is more comfortable and less obtrusive for the patient to wear. The catheter effectively bypasses any obstructions in the patient's nasal cavity and nasopharynx. The high flow of gas can also helps to relieve any obstruction between the nasopharynx and trachea (e.g., obstruction by the tongue). The flow of air/oxygen is thoroughly humidified, which reduces accumulation of mucus and drying of the patient's airway. There are no constraints on the patient during periods when the patient is not receiving therapy. In addition, the present system can be used to deliver a variety of gases including air (for sleep apnea and neuromuscular disorders), air and oxygen (for hypoxemia), and helium and oxygen (for enhanced gas transport and other physiologic benefits, such as reduced work of breathing).

Issues

The following issues are on appeal:

1. Whether claims 1 - 4, 8, 11 - 17, 19, 20, 23 - 25, and 28 were improperly rejected under 35 U.S.C. §103(a) as being unpatentable over Brekke?

2. Whether claims 5, 6, and 18 were improperly rejected under 35 U.S.C. §103(a) as being unpatentable over Brekke in view of Dali et al.?

3. Whether claims 7 and 19 were improperly rejected under 35 U.S.C. §103(a) as being unpatentable over Brekke in view of Spofford et al.?

4. Whether claims 9, 10, 21, 22, 26, and 27 were improperly rejected under 35 U.S.C. §103(a) as being unpatentable over Brekke in view of Daniell et al.?

Grouping of Claims.

Claims 1 - 4, 8, 11 - 17, 19, 20, 23 - 25, and 28 stand or fall together. The patentability of these apparatus claims turns on whether each is obvious over Brekke.

Claims 5, 6, and 18 include limitations relating to connectors for the device, and therefore stand or fall together. The patentability of these claims turns on whether each is obvious over Brekke in view of Dali et al.

Claims 7 and 19 include the limitation of a hydrophilic coating, and therefore stand or fall together. The patentability of these claims turns on whether each is obvious over Brekke in view of Spofford et al.

Claims 9, 10, 21, 22, 26, and 27 include limitations requiring regulation of the temperature or humidity of the gas delivered through the nasal catheter, and therefore

stand or fall together. The patentability of these claims turns on whether each is obvious over Brekke in view of Daniell et al.

Argument

Issue 1

The Appellant asserts that the final Office Action improperly rejected claims 1 - 4, 8, 11 - 17, 19, 20, 23 - 25, and 28 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Brekke. Unlike Brekke, each of the independent claims 1, 15, and 23 require that the present invention is an "open" system to supplement a patient's spontaneous respiration in treatment of respiratory failure, respiratory insufficiency, or sleep apnea syndrome.

To fully understand the importance of the structure of the present invention and to completely understand the distinct benefits that result from the intended use of the present invention, it is important to have knowledge of the pathophysiology of respiratory failure, respiratory insufficiency, and sleep apnea. Respiratory failure and insufficiency occur when diseases or disorders of the respiratory system prevent carbon dioxide from being exhaled and/or inadequate amounts of oxygen from entering the blood during spontaneous breathing of ambient or atmospheric air. When there is an impairment of the alveolocapillary membrane, mismatch of ventilation and blood flow, or underventilation due to a lung disease or disorder, inadequate amounts of oxygen may enter the blood during spontaneous breathing of ambient or atmospheric air. Respiratory failure and insufficiency can be acute, chronic, or acute superimposed upon chronic. Respiratory failure and insufficiency can cause carbon dioxide retention because:

1. The respiratory muscles fatigue due to increased work of breathing and the consequence is inadequate spontaneous breathing of ambient air; and/or

2. Impaired central ventilatory drive results in inadequate spontaneous breathing of ambient air in and out of the lungs.

Similarly, sleep apnea occurs when, during spontaneous breathing of ambient or atmospheric air, inadequate volumes of air reach the lungs (causing low blood oxygen levels) and carbon dioxide is not adequately exhaled. Sleep apnea can be caused by:

1. Upper airway obstruction, where tissue planes in the upper airway are "sucked" together causing obstruction on inspiration. Inadequate spontaneous breathing of ambient air then occurs. With total occlusion, there is cessation of breath, or "apnea," and with partial obstruction there is an inadequate breath (hypopnea), which often generates a snoring sound. Obstruction is often at the level of the soft palate. Uvulopalatopharyngoplasty (the surgical removal of this level of obstruction) corrects sleep apnea in about 50% of patients, demonstrating that the significant obstruction is at this level in about 50% of patients. A second area of obstruction is often at the base of the tongue and hypopharynx; and/or

2. Impaired central ventilatory drive which also results in inadequate spontaneous breathing of ambient air in and out of the lungs.

The Brekke Device. Brekke's invention is used to deliver anesthetic and/or oxygen for surgical procedures in the operating room, oral surgery office, or out-patient clinic that require access to the oral cavity, face, and neck. Brekke discloses three embodiments or configurations:

1. The first embodiment features an endotracheal tube 16 and is intended for use with a ventilator, such as in an operating room, as discussed at column 3, lines 25, et seq. (environment I) The patient's trachea is blocked by an endotracheal tube cuff 20 and an inflatable barrier 18 seals the back of the oral cavity, as shown in figure 1 of the Brekke patent. Sponge rubber collars 34 and 36 also seal the patient's nostrils around the periphery of the nasal cannula 26 to obstruct spontaneous respiration through the nose. The patient is solely dependent on the fluctuating gas flow and volume supplied by the ventilator to simulate and support the respiratory cycle.

2. The second embodiment replaces the endotracheal tube with a nasalpharyngeal tube 44, which is used by an oral surgeon in an out-patient clinic or oral surgery office for administering anesthetic (environment II). It is only inserted after intravenous anesthetics have been administered to render the patient unconscious (column 5, line 20 - 21). Here again, an inflatable barrier 18a seals the back of the oral cavity to prevent aspiration of blood, saliva, and debris into the lungs. Sponge rubber collars 34, 36 block the nostrils. The patient is apparently intended to breathe in and out through the nasalpharyngeal tube 44 and nasal cannula 26. Anesthetics and oxygen are delivered via the nasalpharyngeal tube. A one-way exhaust valve 38 on the cannula 26 allows the patient to exhale through the nasal cannula 26.

3. The third configuration uses the nasal cannula 26 by itself (without an endotracheal tube or nasalpharyngeal tube) to administer nitrous oxide or oxygen, as discussed at col. 4, lines 60 et seq. of Brekke. This configuration is essentially little different than a conventional nasal cannula.

Brekke's first embodiment teaches away from the present invention by disclosing an endotracheal tube for use in a "closed" system in which spontaneous breathing is blocked by the endotracheal tube cuff 20 in the patient's trachea, the inflatable barrier 18 sealing the back of the patient's oral cavity, and the sponge rubber collars 34, 36 blocking the nostrils. Brekke discusses that his device can be used to administer anesthetic gases to a patient. A closed system is required for this purpose to prevent the escape of certain anesthetic gases into the surrounding room and to control the anesthetic dose to the patient. In addition, the patient must be sedated or unconscious to tolerate insertion of an endotracheal tube without stimulating the gag reflex. Likewise, as with all surgeries requiring an endotracheal tube, sedation must be continued during the operative procedure so the patient will continue to tolerate the endotracheal tube.

Brekke's second embodiment also teaches away from the present invention. It too is a closed system in which an inflatable barrier 18a seals the back of the patient's oral cavity, and sponge rubber collars 34, 36 block the nostrils. Here again, the patient must be rendered unconscious to tolerate insertion of the nasalpharyngeal tube 44 with an inflated cuff 18a without stimulating the gag reflex (column 5, lines 20 - 21). Anesthetic gas and sedation are continued through the procedure. The patient's reduced level of consciousness during the operation makes the patient prone to aspirating bone, blood and debris into the lungs. Though the barrier is designed to prevent aspiration, sedation must be continued to eliminate the gag reflex induced by the inflatable barrier.

Structure and Use of the Present Invention. In contrast to the closed systems disclosed by Brekke, the present invention is an "open" system in which a nasal catheter provides air/oxygen to supplement the patient's spontaneous breathing without obstructing the patient's spontaneous breathing. In some cases, this can be enough to prevent having to put a patient with respiratory failure or insufficiency on ventilator life support with an endotracheal tube. Similarly, the high flow delivered through the nasopharyngeal catheter actually opens up the upper airway and prevents obstruction in patients with obstructive

sleep apnea. The present invention can be used for extended periods of time or just periodically as needed by the patient. For example, the present invention can be used by a patient on a nightly basis to treat sleep apnea. The nasal catheter can be readily inserted and removed without patient sedation. It also allows the patient to continue talking, eating, and drinking in a normal manner, unlike Brekke.

As noted above, a primary purpose of an open system is to treat patients with respiratory failure or insufficiency, or sleep apnea syndrome, so that a ventilator will not become necessary. However, being placed on a closed system is often enough to push such a patient "over the edge." Patients with respiratory failure or insufficiency or sleep apnea have markedly increased work of breathing. It is not realistic to expect a patient with an impaired respiratory system to breathe in and out through a small-diameter tube without ventilator assistance in performing the work of breathing. The increased resistive loads caused by breathing in and out through a small-diameter tube can further fatigue the respiratory muscles. In addition, insertion and maintenance of an endotracheal tube or nasalpharyngeal tube into the trachea, as taught by Brekke, requires that the patient must be unconscious or sedated to avoid stimulating the patient's gag reflex. Sedation or anesthesia markedly impairs the neurologic respiratory drive and is contra-indicated for patients with respiratory failure or insufficiency, or sleep apnea syndrome who must rely on their spontaneous respirations.

All of the independent claims in the present application also require that the distal end of the nasal catheter supplies air/oxygen into the patient's distal nasopharynx or oropharynx (claim 1, lines 6 - 8; claim 15, lines 6 - 8; and claim 23, lines 5 - 7). In contrast, the distal end of the endotracheal tube disclosed by Brekke extends past the patient's nasopharynx, oropharynx, and larynx, and into the patient's trachea.

Furthermore, all of the independent claims require a continuous gas flow rate of approximately 4 to 40 liters per minute. Flow is one-way through the catheter and the patient does not exhale back through the device. This high flow rate of gas is delivered into the patient's distal nasopharynx or oropharynx, at a point relatively high in the patient's

respiratory tree. A portion of this gas flows into the patient's trachea and lungs to deliver oxygen, flush carbon dioxide from the patient's lungs, reduce physiologic dead space and reduce the work of breathing. If the gas delivered by the catheter has an elevated oxygen content, it will tend to enrich the oxygen content of all of the gas in the patient's respiratory tree, and thus makes the patient's spontaneous breathing more effective. However, a large portion of the gas exiting the catheter is exhaled or flows unrestricted out of the patient's airway and is lost. Continuous flow rates of 4 to 40 liters per minute are physiologically possible with open systems because excess gas can readily escape from within the patient. However, this is not possible with a closed system such as Brekke in which the airway is blocked by the endotracheal tube cuff 20 in the patient's trachea and the inflatable barrier 18 sealing the back of the patient's oral cavity. In such a closed system, the ventilator must precisely follow a sinusoidal curve for the delivery of flow and volume that simulates a breath. Preset maximum and minimum values are dictated by the patient's respiratory capacity. In patients with impaired lung and respiratory muscle capacity, a continuous flow that is also delivered on exhalation through a small-diameter nasalpharyngeal tube in a closed system will build up backpressure and an increased resistance to exhalation through the tube. This pressure can cause further injury to the lungs and fatigue of already compromised respiratory muscles through increased work load.

Regarding claims 2 - 3, 15 - 22 and 24, nothing in Brekke teaches or suggest a catheter that can be trimmed to a desired length. The endotracheal tube disclosed by Brekke has a fixed length. The cuff at the distal end of the endotracheal tube and the conduits at the upper end of the Brekke device would make it impossible to trim such a device while maintaining its intended functionality. Column 4, lines 46 *et seq.* of the Brekke patent discusses adjusting the position of the nasalpharyngeal tube in Brekke's second embodiment, but not trimming its length. With regard to claims 24 and 25, nothing in Brekke teaches or suggests cutting the catheter so its distal tip will have a desired position relative to the patient's uvula.

The intended use of the present invention is very different than the intended use of the Brekke device. The purpose of the present device is to treat acute and chronic respiratory failure and respiratory insufficiency as well as sleep apnea by augmenting spontaneous breathing of ambient or atmospheric air. In particular, the present invention offers two main benefits for the treatment of respiratory failure and insufficiency:

1. One major benefit of the gas flow through the present catheter is the effect on dead space. Anatomical dead space is the volume contained within the entire upper airway and the tracheobronchial tree. Physiologic dead space is the sum of anatomic dead space plus the volume of dead space gas in nonfunctioning alveoli due to respiratory diseases or disorders. The normal anatomical dead space of the average sized person is 150 ml. The upper airway constitutes the major portion of the anatomical dead space. The total volume displaced by the nasal pharyngeal catheter described in his application is less than 3 to 4 ml. Though the volume of anatomical dead space is smaller in infants and children, the diameter and length of the catheter are proportionately smaller. The small volume of the catheter relative to the anatomical dead space prevents obstruction of the spontaneous breathing of ambient or atmospheric air. In addition, at the end of exhalation the dead space is filled with gas that exited the alveoli, which is low in oxygen and high in CO_2. At the beginning of the next inspiration, this low oxygen and high CO_2 is re-breathed into the alveoli. With the tip of the catheter in the distal nasopharynx or oropharynx, the high flow of pure oxygen or an oxygen enriched gas washes out the low oxygen/high CO_2 dead space gas into the atmosphere and replaces it with a high oxygen environment. This increases the fraction of inspired oxygen (FIO_2) for the subsequent inspiration and helps correct inadequate blood oxygen levels. Similarly, high

flows of pure oxygen or an oxygen-enriched gas mixture delivered from the catheter can directly enter the lungs, improving oxygen delivery. In a similar fashion to what is described above, the re-breathing of the high CO_2 gas contained within the anatomic or physiologic dead space can be detrimental to individuals who will retain CO_2 due to either respiratory muscle fatigue, impaired central respiratory drive, or both. With the tip of the catheter in the distal nasopharynx or oropharynx, the high flow from the catheter of oxygen or an oxygen enriched gas washes out the high CO_2 dead space gas into the atmosphere during exhalation. Respiratory failure and insufficiency are improved by washing out the dead space during exhalation, facilitating the exhalation of carbon dioxide during spontaneous breathing of ambient or atmospheric air.

2. A second major benefit of the catheter design is that the high flow of gas directed at the trachea can generate gas flow and volume into the lungs, reducing the required work of breathing and helping correct for the inadequate spontaneous breathing of ambient air in and out of the lungs in the presence of the reduced central ventilatory drive. High flows of oxygen or oxygen enriched gas delivered from the catheter during inspiration can directly enter the lungs, reducing the work of breathing required to physically draw the gas in. The flow of gas from the catheter directly into the lungs during inspiration can also washout CO_2 from the tracheobronchial tree.

In sleep apnea, an impaired central ventilatory drive also results in inadequate spontaneous breathing of ambient air in and out of the lungs. As with respiratory failure or insufficiency due to an impaired central ventilatory drive, in the presence of central sleep apnea, the high flow of air or oxygen enriched air from the catheter can contribute to the volume of gas delivered to the lungs, which helps correct for the inadequate spontaneous breathing of ambient air. Furthermore, flow from the catheter on expiration

can wash CO_2 out of the dead space and into the atmosphere, which improves the condition.

As noted before, the obstruction and obstructive sleep apnea is often at the level of the soft palate. When the catheter is placed past the soft palate and into the superior aspect of the oropharynx, high flows of gas from the catheter on inspiration bypass the obstruction, improving the flow of gas into the lungs, which helps correct for the inadequate spontaneous breathing of ambient air due to the obstruction. When the obstruction is at the level of the base of the tongue or below, high flows on inspiration can keep the airway from collapsing. Consequently, high inspiratory flows of gas from the catheter can relieve the obstruction at the level of the base of the tongue or below, correcting for the inadequate spontaneous breathing of ambient air due to the obstruction. Furthermore, flows through the catheter on expiration can keep the opposing mucus membranes in the area of the soft palate and in the areas at the tongue or below from coming in contact, thus reducing the tendency for the airway to collapse on the subsequent inspiration.

The present invention provided additional benefits in treatment of respiratory failure/insufficiency and sleep apnea. The design of the present catheter allows it to be inserted without any sedation or alteration of consciousness. The catheter can be inserted by the patient. In contrast, the nasopharyngeal tube of Brekke must be inserted in an unconscious patient to be tolerated. If the Brekke nasopharyngeal tube was inserted in the conscious patient described in the present invention, the tip of the catheter in the hypopharynx would cause a gag reflex to the point of vomiting (in the same fashion that sticking a finger down your throat into the hypopharynx induces vomiting). Furthermore, the presence of an object in the hypopharynx is the strongest stimulus to initiate a swallowing reflex, which would induce aerophagia, or swallowing of gas into the esophagus. This can cause stomach distention and rupture. The presence of an inflated balloon pressing on multiple mucosal surfaces would also cause an intense gag reflex.

The current catheter design allows it to be used continuously in the treatment of acute respiratory failure for a number of days. The current catheter design also allows it to be use nightly for many years in patients with chronic respiratory failure or insufficiency and sleep apnea. The nasopharyngeal tube of Brekke is designed to be used for short operative procedures in medically stable patients.

The present invention allows the awake patient to eat and drink during treatment. The nasopharyngeal tube of Brekke is designed to be used in the classic operative setting or outpatient setting where patients have not been fed and have an empty stomach. Eating or drinking with the tube in place would not be possible with the inflatable oral barrier, but this is not an issue because patients must be unconscious to tolerated it.

Based on the design and intended use of the present catheter, the flow rate is important. As noted previously, gas from the catheter can be delivered directly into the trachea to increase the volume delivered to the lungs, to increase the oxygen content delivered to the lungs, and to increase the CO_2 that is washed out of the tracheobronchial tree. The flow into the lungs during inspiration and out during expiration is sinusoidal. The average peak flow during tidal spontaneous breathing of ambient air is approximately 30 L/min. A maximum flow of 40 L/min should be adequate to meet this peak inspiratory flow demand. Furthermore, it is noted that under some conditions the major intended use of the catheter is to wash out the gas in the upper airway dead space and replace it with gases of a different property that flow through the catheter. On the low-end of the flow spectrum are the requirements for flushing out the upper airway of infants and children that have a smaller upper airway dead space volume. The flow rate of 4 L/min will meet these needs.

Issues 2 - 4

Claims 5, 6, and 18 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Brekke in view of Dali et al. Claims 7 and 19 have been rejected under

35 U.S.C. §103(a) as being unpatentable over Brekke in view of Spofford et al. Claims 9, 10, 21, 22, 26, and 27 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Brekke in view of Daniell et al. Appellant notes that each of these are dependent claims. In response, Appellant restates the previous comments concerning Brekke, and submits that the invention defined in each of these dependent claims should be considered as a whole. The specific elements provided by each of these dependent claims should be considered in combination with the elements of their respective independent claims, rather than as isolated elements by themselves.

Summary

For the foregoing reasons, the Appellant believes that the rejections of claims 1 - 28, as set forth in the final Office Action, were erroneous. Therefore, Appellant respectfully urges the Board to allow the claims.

A check is enclosed in the amount of $160.00 pursuant to 37 C.F.R. §1.17(c) for filing a brief in support of an appeal for a small entity. If any fees in addition to those already paid are required, please debit Deposit Account 04-1414.

Respectfully submitted,

DORR, CARSON, SLOAN & BIRNEY, P.C.

Date: April 4, 2003

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APPENDIX

1. A nasopharyngeal catheter for open delivery of a continuous flow of air/oxygen into a patient's distal nasopharynx or oropharynx to supplement a patient's spontaneous respiration in treatment of respiratory failure, respiratory insufficiency, or sleep apnea syndrome, said nasopharyngeal catheter comprising:

a nasal catheter having a proximal end and a distal end adapted to extend through a patient's nose and into the patient's distal nasopharynx or oropharynx without obstructing the patient's spontaneous respiration;

a delivery tube adapted to extend below the patient's nostril connected to the proximal end of the nasal catheter; and

a gas source delivering a continuous flow of air/oxygen at a rate of approximately 4 to 40 liters per minute through the delivery tube and nasal catheter into the patient's distal nasopharynx or oropharynx.

2. The nasopharyngeal catheter of claim 1 wherein the nasal catheter comprises a flexible plastic tube that can be cut to a desired length.

3. The nasopharyngeal catheter of claim 2 wherein the nasal catheter further comprises a plurality of markings indicating a series of common lengths for the nasal catheter.

4. The nasopharyngeal catheter of claim 1 wherein the nasal catheter further comprises a radio-opaque stripe.

5. The nasopharyngeal catheter of claim 1 wherein the delivery tube further comprises;

two opposing ends with connectors for removable attachment to the gas source; and

a cap removably insertable into a connector that is not attached to the gas source.

6. The nasopharyngeal catheter of claim 1 further comprising a connector for removably attaching the proximal end of the nasal catheter to the delivery tube.

7. The nasopharyngeal catheter of claim 1 wherein the nasal catheter further comprises a hydrophilic coating.

8. The nasopharyngeal catheter of claim 1 wherein the nasal catheter has an inside diameter of approximately 3 mm.

9. The nasopharyngeal catheter of claim 1 further comprising a humidifier controlling the humidity of the gas delivered through the nasal catheter.

10. The nasopharyngeal catheter of claim 1 further comprising a heater controlling the temperature of the gas delivered through the nasal catheter.

11. The nasopharyngeal catheter of claim 1 wherein gas is supplied through the nasal catheter at a back pressure of approximately 2 to 25 psi.

12. The nasopharyngeal catheter of claim 1 wherein the gas supplied through the nasal catheter comprises oxygen.

13. The nasopharyngeal catheter of claim 1 wherein the gas supplied through the nasal catheter comprises air.

14. The nasopharyngeal catheter of claim 1 wherein the gas supplied through the nasal catheter comprises helium.

15. A nasopharyngeal catheter for open delivery of a continuous flow of air/oxygen into a patient's distal nasopharynx or oropharynx to supplement a patient's spontaneous respiration in treatment of respiratory failure, respiratory insufficiency, or sleep apnea syndrome, said nasopharyngeal catheter comprising:

a nasal catheter having a proximal end and a distal end adapted to extend through a patient's nose and into the patient's distal nasopharynx or oropharynx without obstructing the patient's spontaneous respiration, said catheter being made of a flexible material that can be trimmed to a desired length;

a delivery tube adapted to extend below the patient's nostril having a connector for removable attachment to the proximal end of the nasal catheter; and

a gas source delivering a continuous flow rate of approximately 4 to 40 liters per minute through the delivery tube and nasal catheter into the patient's distal nasopharynx or oropharynx.

16. The nasopharyngeal catheter of claim 15 wherein the nasal catheter further comprises a plurality of markings indicating a series of common lengths for the nasal catheter.

17. The nasopharyngeal catheter of claim 15 wherein the nasal catheter further comprises a radio-opaque stripe.

18. The nasopharyngeal catheter of claim 15 wherein the delivery tube further comprises;

two opposing ends with connectors for removable attachment to the gas source; and

a cap removably insertable into a connector that is not attached to the gas source.

19. The nasopharyngeal catheter of claim 15 wherein the nasal catheter further comprises a hydrophilic coating.

20. The nasopharyngeal catheter of claim 15 wherein the nasal catheter has an inside diameter of approximately 3 mm.

21. The nasopharyngeal catheter of claim 15 further comprising a humidifier controlling the humidity of the gas delivered through the nasal catheter.

22. The nasopharyngeal catheter of claim 15 further comprising a heater controlling the temperature of the gas delivered through the nasal catheter.

23. An open delivery method for providing a supplemental continuous flow of air/oxygen to a spontaneously breathing patient in the treatment of respiratory failure, respiratory insufficiency, or sleep apnea syndrome, the method comprising:

advancing a nasopharyngeal catheter through a patient's nostril until the distal tip of the catheter is located in the patient's distal nasopharynx or oropharynx without obstructing the patient's spontaneous respiration; and

supplying air/oxygen through the catheter at a continuous flow rate of approximately 4 to 40 liters per minute into the patient's distal nasopharynx or oropharynx.

24. The method of claim 23 further comprising the initial steps of:

providing a delivery tube extending beneath the patient's nostril for delivering the flow of air/oxygen, said delivery tube having a connector for attachment to the catheter;

advancing the catheter through a patient's nostril until the distal tip of the catheter is visible through the patient's mouth below the patient's uvula;

cutting the proximal end of the catheter to a desired length so that the distal tip of the catheter will have a desired position relative to the patient's uvula;

attaching the proximal end of the catheter to the connector on the delivery tube.

25. The method of claim 23 further comprising the initial step of selecting the length of the catheter by advancing a catheter through a patient's nostril until the distal tip of the catheter is visible through the patient's mouth below the patient's uvula.

26. The method of claim 23 further comprising controlling the humidity of the air/oxygen supplied through the catheter.

27. The method of claim 23 further comprising regulating the temperature of the air/oxygen supplied through the catheter.

28. The method of claim 23 further comprising supplying helium through the catheter.